REMARKS

Claim Amendments

Claims 1-12, 25-32, and 35-48 are pending. Claims 1-3, 12, 25, and 26 are amended. Claims 40-48 are added. Claims 13-17, 19, 21-24, and 33-34 are canceled without prejudice or disclaimer to the subject matter therein. Applicants reserve their right to prosecute the canceled subject matter in one or more divisional applications. Support for the amendments may be found throughout the specification and claims as originally filed. *See, e.g.*, ¶¶ [0050], [0067]-[0076] [0081], [0085], [0102], and [0105].

Specification

The USPTO objects to the specification because it contains an embedded hyperlink and/or other form of browser-executable code.

The specification has been amended to delete the embedded hyperlinks and/or other form of browser-executable codes. Accordingly, this objection is moot.

Drawings

The USPTO objects to the drawings because Figure 1 has allegedly been omitted.

Applicants respectfully submit that Figure 1 was submitted to the USPTO. Indeed, US 2008/0022421, the publication of the instant application, contains Figure 1. Accordingly, Applicants request clarification of this objection.

Rejections Under 35 U.S.C. § 112, 1st Paragraph

Claims 1-12, 25-32, and 35-39 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the overexpression of SEQ ID NO: 3 for increasing activity in at least one OK1 protein in plant that also expresses glucan, water dikinase, allegedly does not enable the full scope of the claimed invention.

As amended, the claims are directed to nucleic acid molecules, plant cells and plants comprising nucleic acid molecules having a particular structure and function. Applicants submit that the specification provides the requisite guidance for one of skill in the art to make and use the claimed nucleic acid molecules, plant cells and plants.

Applicants also provide the following comments in response to the Office Action.

The USPTO asserts that the activity of an OK 1 protein is dependent on previous phosphorylation of starch by an R1 protein.[2] The USPTO appears to contend that it would require undue experimentation for the skilled artisan to determine which plants express R1 proteins.[3]

Applicants respectfully disagree. As an initial matter, Applicants point out that an OK 1 protein phosphorylates already prephosphorylated starch.[4] As such, one of skill in the art does not need to determine which plants express an R1 protein. Rather, the skilled artisan need only know if the respective plant produces phosphorylated starch. This can be determined by methods well known in the art.[5] Applicants note that Hijazi and Ritte, cited by the USPTO, show that a person skilled in the art would understand that almost all plants synthesize phosphorylated starch.[6] Accordingly, it would not require undue experimentation to identify plants comprising R1 proteins or to select plants that produce phosphorylated starch.

The USPTO further asserts that the specification does not provide any guidance as to OK 1 proteins.[7] Specifically, the USPTO contends that both OK 1 proteins and R1 proteins contain a phosphohistidine domain.[8]

Applicants respectfully disagree and submit that the specification teaches: (1) several OK 1 proteins;[9] (2) methods for evaluating whether a protein has OK 1 activity;[10] and (3)

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[2] *See* Office Action, page 4 (citing Hejazi).

[3] *See id.* at pages 4-6.

[4] *See* Specification, ¶ [0025].

[5] *See* Specification, ¶ [0034].

[6] Ritte, page 4872, left column, 1st sentence of "Introduction" ("Starch of most plant sources contains a low percentage of glucosyl residues that are monoesterified with phosphate"); Hejazi, page 324, left column, end of 3rd paragraph ("GWD and PWD .... are both required for the normal metabolism of transitory starch and for development of the entire plant as well."); *see also* Specification, ¶ [0010] (disclosing numerous references to R1 nucleic acid and protein sequences).

[7] Office Action, page 5.

[8] *Id.*

[9] *See* SEQ ID NOS: 2 and 4.

that OK 1 proteins contain a phosphohistidine (SEQ ID NO: 5). Applicants also point out that the phosphohistidine domains of OK1 and R1 proteins are quite different. Indeed, there are two histidine residues in OK 1 proteins, whereas R1 proteins comprise a single histidine residue.[11] Furthermore, the phosphohistidine domain of an OK 1 protein (SEQ ID NO: 5) shares only 58.3% identity with the phosphohistidine domains of R1 proteins.[12] Accordingly, the specification provides the requisite guidance as to OK 1 proteins.

The USPTO finally asserts that because the phosphorylation of starch requires GWD (R1) and that a different, phosphorylating dikinase protein (AtGWD2) is not fully characterized, it would require undue experimentation to determine whether the starch of a plant would be phosphorylated by OK 1.[13]

Applicants respectfully disagree. As an initial matter, Applicants respectfully request clarification as to why an uncharacterized putative protein like AtGWD2 would have any impact on the predictability of an OK 1 protein.[14] Nonetheless, as discussed above, OK 1 proteins phosphorylate already prephosphorylated starch, methods of determining phosphylorated starches is well known in the art, and the specification teaches one of skill in the art how to evaluate whether a protein has OK 1 activity. Accordingly, the specification provides the requisite guidance to determine whether the starch of a plant would be phosphorylated by OK 1.

In view of the foregoing, Applicants respectfully request withdrawal of the enablement rejection.

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[10] *See, e.g.*, Specification, ¶¶ [0036]-[0043]; "General Methods"; Example 11.

[11] *See, e.g.*, Specification, ¶ [0028]; SEQ ID NO: 5.

[12] *See* Sequence Alignment, **Exhibit A**; *see also* Kötting et al. (**Exhibit B**), at Figure 2 (showing that an OK 1 protein shares only 7 out of 12 amino acids with R1 proteins).

[13] *See* Office Action, page 5 (citing Ritte).

[14] Applicants submit that AtGWD2 has nothing to do with starch phosphorylation in plants. *See* Glaring et al. (2007) (**Exhibit C**), at page 3954, right column, 1st paragraph, last sentence (teaching mutants lacking AtGWD2 have a normal starch metabolism); page 3957, right column, end of 2nd paragraph under "Discussion" ("Analysis of *Arabidopsis* mutants demonstrated that the enzyme is not required for the degradation of transient starch, suggesting that AtGWD2 is active on an, as yet unidentified, glucan substrate.").

Claims 1-12, 25-32, and 35-39 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement.

As amended, the claims are directed to nucleic acid molecules, plant cells and plants comprising nucleic acid molecules having a particular structure and function. Furthermore, the specification teaches: (1) several OK 1 proteins;[15] (2) methods for evaluating whether a protein has OK 1 activity;[16] and (3) that OK 1 proteins contain a phosphohistidine (SEQ ID NO: 5). Accordingly, Applicants submit that specification describes the claimed subject matter in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In view of the foregoing, Applicants respectfully request withdrawal of the written description rejection.

Rejections Under 35 U.S.C. § 102

Claims 1-2 and 4-12 stand rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by U.S. Pat. No. 6,521,816 ("the '816 patent") in light of Ritte et al. (FEBS Letters 580:4872-4876, 2006).

As amended, the claims are directed to nucleic acid molecules, plant cells and plants comprising nucleic acid molecules having a particular structure and function. The '816 patent does not teach or suggest the claimed nucleic acid molecules. Indeed, Applicants point out that claim 25, which recites nucleic acid molecules now present in claims 1 and 12, was not rejected over the '816 patent. Accordingly, the '816 patent does not anticipate the claimed invention.

In view of the foregoing, Applicants respectfully request withdrawal of this rejection.

Claims 1-8, 10-12, 25-32, and 35-39 stand rejected under 35 U.S.C. § 102(e), as allegedly being anticipated by U.S. 20060123505 ("Kikuchi").

The claimed nucleic acid molecules encode OK 1 proteins. An OK 1 protein is a protein that transfers a phosphate residue of ATP onto already phosphorylated starch.[17] The

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[15] *See* SEQ ID NOS: 2 and 4.

[16] *See, e.g.*, Specification, ¶¶ [0036] to [0043]; "General Methods"; Example 11.

[17] *See* Specification, ¶ [0025].

claimed nucleic acid molecules, when introduced into a plant cell, increase the activity of at least one OK 1 protein in the plant cell. The increase in OK 1 activity leads to a starch having an increased or modified phosphate content. Prior to the instant invention, it had not been possible to increase the starch phosphate content of already phosphorylated starch in plants above a certain quantity.[18] Accordingly, the inventors of the instant application identified novel sequences having a unique activity.

Kikuchi discloses 28,469 cDNA sequences.[19] Kikuchi does not disclose that any of these sequences is involved in starch metabolism or has OK 1 activity. Indeed, Kikuchi is completely silent with respect to the activity of SEQ ID NO: 22133 (which is purportedly 99.5% identical to SEQ ID NO: 3).[20] Kikuchi also fails to provide any guidance to one of skill in the art to select SEQ ID NO: 22133 out of the 28,469 sequences. To be sure, Kikuchi does not suggest any preference for SEQ ID NO: 22133, or for introducing this sequence into a plant cell to increase OK 1 activity.

In the recent case of *Sanofi-Synthelabo v. Apotex, Inc.*,[21] the Court of Appeals for the Federal Circuit considered whether a reference disclosing a racemate and containing a statement that the racemate consists of enantiomers constituted an anticipating disclosure of a separated enantiomer of the racemate.[22] In holding the reference to be non-anticipatory, the Court stated the prior art racemate "is shown in the references as one of several compounds with desirable biological properties," and that the prior art "would not have led one of ordinary skill in the art to recognize either an explicit or an inherent disclosure of its dextrorotatory enantiomer, as well as the bisulfate salt."[23] The Court referred to older cases such as *In re Petering* and *In re Schaumann*, which stand for the proposition that when the prior art divulges a very large list of compounds from which to make a selection, there must be

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[18] *Id.* at ¶ [0031].

[19] *See* Kikuchi, ¶ [0011].

[20] Applicants note that the Office Action does not contain a sequence alignment between SEQ ID NO: 22133 and instant SEQ ID NO: 3.

[21] *Sanofi-Synthelabo v. Apotex, Inc.*, 89 USPQ2d 1370 (Fed. Cir. 2008).

[22] *Id.* at 1375.

[23] *Id.*

some "specific preferences" set forth that would direct one of ordinary skill in the art to the claimed compound.[24] It will be appreciated that this principle applies both where there is a specific listing as well as where there is a generic formula disclosed.

Similarly, in *Abbott Laboratories* v. *Sandoz*,[25] Sandoz alleged that a reference disclosing a large list of polymers encapsulating an antibiotic anticipated Abbott's claim to a particular polymer encapsulating the antibiotic. Again, the Federal Circuit noted that the list of compounds would not have put a person skilled in the art in possession of Applicants claimed composition.[26]

Likewise, in the instant case, SEQ ID NO: 22133 is one of many sequences disclosed. There is nothing in Kikuchi that "would not have led one of ordinary skill in the art to recognize either an explicit or an inherent disclosure" of a nucleic acid sequence encoding an OK 1 protein or a plant cell comprising a foreign nucleic acid molecule, wherein the plant cell exhibits increased activity in at least one OK1 protein and synthesizes a modified starch. Alternatively, there is nothing in Kikuchi that sets forth a "specific preference" for SEQ ID NO: 22133. Accordingly, Applicants respectfully submit that Kikuchi does not anticipate the claimed invention.

In view of the foregoing, Applicants respectfully request withdrawal of this rejection.

Double Patenting

Claim 12 stands provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of co-pending U.S. Application No. 10/591,540.

Applicants request that this rejection be held in abeyance until allowable subject matter is identified.

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[24] *Id.*

[25] *Abbott Laboratories* v. *Sandoz*, 89 USPQ 2d 1161 (Fed. Cir. 2008).

[26] *Id.* at 1166.

CONCLUSION

In view of the foregoing, Applicants respectfully request an indication of allowance of all claims.

If the Examiner has any questions relating to this response, or the application in general, he is respectfully requested to contact the undersigned so that prosecution of this application may be expedited.

Respectfully submitted,

HUNTON & WILLIAMS LLP

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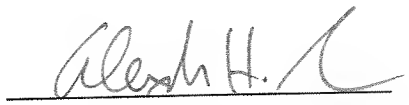
By: 

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